CHAMPVA POLICY MANUAL

CHAPTER: 2
SECTION: 31.12
TITLE: COMBINED HEART-KIDNEY TRANSPLANTATION

AUTHORITY: 38 CFR 17.270(a), 17.272(a)(1)(4)(13)(14)(59), and 17.273

RELATED AUTHORITY: 32 CFR 199.4(e)(5)

I. EFFECTIVE DATE

March 27, 1997

August 1, 2003, for combined heart-kidney transplant, payment will be made under the assigned DRG based on the patient's diagnosis.

II. PROCEDURE CODE(S)

33940-33945, 50300-50380, (ICD-9-CM - 55.69)

III. POLICY

A. Combined heart-kidney transplantation requires preauthorization.

B. Criteria contained in this policy must be followed when authorizing combined heart-kidney transplantation.

C. Affirmative Patient Selection Criteria. Medically necessary services and supplies related to combined heart-kidney transplants are covered when the transplant is performed at a Medicare, TRICARE, or VA approved transplant center. All of the following criteria must be met:

1. are suffering from end stage heart disease and irreversible or end stage renal disease;

2. must have exhausted more conservative medical and surgical treatments;

3. must have a realistic understanding of the range of clinical outcomes that may be encountered; and

4. beneficiaries must have plans for long-term adherence to a disciplined medical regimen that are feasible and realistic.

D. Benefits may be allowed for medically necessary services and supplies during the Medicare waiting period for those beneficiaries who qualify for Medicare coverage as a result of end stage renal disease.

E. For a properly preauthorized patient, medically necessary services and supplies related to combined heart-kidney are cost shared for:

1. The evaluation of a potential candidate's suitability for transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. The pre- and post-transplantation inpatient hospital and outpatient services.

3. The pre- and post-operative services of the transplantation team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and donated organ to the location of the transplantation center is covered.

5. The maintenance for viability of the donor organ is covered after all existing legal requirements for excision of the donor organ has been met.

6. The blood and blood products required for the transplantation.

7. FDA approved immunosuppression drugs, to include off-label uses, when determined to be medically necessary and generally accepted practice within the medial community (i.e., proven).

8. The complications associated with the transplant procedure, including inpatient care, management of infection, and rejection episodes.

9. The periodic evaluation and assessment of the successfully transplanted patient.

F. Hepatitis B and pneumococcal vaccines for patients undergoing transplantation are covered.

G. DNA-HIA tissue typing for determining histocompatibility is covered.

IV. POLICY CONSIDERATIONS

A. Preauthorization and retrospective authorization of combined heart-kidney transplantation must meet the following two requirements:

1. The patient meets (or as of the date of transplantation would have met) patient selection criteria.

2. The transplant facility is (or as of the date of transplantation would have been) Medicare, TRICARE, or VA approved for heart and renal transplantation.

B. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services or supplies otherwise would be covered but for the failure to obtain preauthorization. If preauthorization is not received, the Health Administration Center will review the claim to determine whether the beneficiary's condition meets the clinical criteria for the transplantation.

C. Claims for services and supplies related to the transplantation will be reimbursed based on the billed charges until such time as a DRG is established. Effective August 1, 2003, for combined heart-kidney transplant, payment will be made under the assigned DRG based on the patient's diagnosis.

D. Charges from the donor hospital will be cost shared on an inpatient basis and must be fully itemized and billed by the transplant center under the name of the CHAMPVA patient (see Chapter 2, Section 31.1, *Donor Costs*).

E. Claims for transportation of the donor organ and transplant team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost shared on an inpatient basis. Scheduled or chartered transportation will be cost shared.

F. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard UB-92 claim form under the name of the CHAMPVA patient. The appropriate hospital standard kidney acquisition costs (live donor or cadaver) required for Medicare in every instance must be used as the acquisition cost for purposes of providing benefits.

G. Air ambulance may be cost shared when determined to be medically necessary (see Chapter 2, Section 32.1, *Ambulance Service*).

H. When a properly preauthorized transplant candidate is discharged less than 24-hours after admission because of extenuating circumstances (i.e., the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed) all otherwise authorized services associated with the admission shall be cost shared on an inpatient basis. The expectation at the time of admission was that the patient would remain more than 24 hours.

I. If a beneficiary becomes eligible for Medicare benefits because of end stage renal disease, CHAMPVA is always the secondary payer.

J. When a beneficiary does not qualify for the Medicare end stage renal disease program because they do not have enough work quarters, CHAMPVA is primary payer. Before CHAMPVA benefits can be allowed, a statement from Medicare is required indicating the patient's ineligibility for benefits.

V. EXCEPTIONS

A. Services and supplies for inpatient or outpatient services that are provided prior to and/or after discharge from hospitalization for a combined heart-kidney transplantation performed in an unauthorized Medicare, TRICARE, or VA heart-kidney transplantation center, may be cost shared subject to applicable program policy. Pre-admission services rendered by an unauthorized transplant center may also be cost shared subject to applicable program policies. These exceptions are also applicable to combined heart-kidney transplants performed prior to March 27, 1997.

B. Combined heart-kidney transplants performed on an emergency basis in an unauthorized transplant facility may be cost shared only when the following conditions have been met:

1. The unauthorized center has consulted with the nearest authorized heart-kidney transplantation center regarding the transplantation case.

2. It has been determined and documented by the transplant team physician(s) at the authorized heart-kidney transplantation center that transfer of the patient (to the authorized heart-kidney transplantation center) is not medically reasonable, even though the transplantation is feasible and appropriate.

VI. EXCLUSIONS

A. Combined heart-kidney transplantation is excluded when any of the following contraindications exist:

1. severe pulmonary hypertension (pulmonary vascular resistance above 5 Wood units or pulmonary artery systolic pressure over 65 mm Hg) is not reversible with intravenous agents;

2. active infection;

3. HIV positive;

4. active alcohol or other substance abuse including current use of tobacco (verified abstinence for six months is mandatory);

5. active malignant disease;

6. hepatic dysfunction not explained by the underlying heart failure and not deemed reversible;

7. symptomatic or asymptomatic cerebrovascular disease;

8. systemic hypertension, either at transplantation or prior to development of end stage cardiac disease, that is not controlled, even with multi-drug therapy;

9. history of noncompliance or psychiatric illness of such magnitude as to jeopardize postoperative compliance;

10. recent and unresolved pulmonary infarction or pulmonary nodules;

11. any chronic systemic illness that would limit or preclude survival and rehabilitation after transplantation; or

12. current or recent history of diverticulitis or peptic ulcer disease requires evaluation by a gastroenterology specialist prior to determining candidacy.

B. Services and supplies provided at no cost or if the beneficiary (or sponsor) has no legal obligation to pay. This includes expenses or charges that are waived by the transplantation center. [38 CFR 17.272(a)(1)]

C. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program, unproven procedure). [38 CFR 17.272(a)(13)]

D. Services, supplies or devices, even those used in lieu of the transplantation, when determined to be related or integral to an investigation or experimental (unproven) procedure (see Chapter 2, Section 16.5, *Investigational or Experimental (Unproven) Procedures*). [38 CFR 17.272(a)(14)]

E. Pre-or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members). [38 CFR 17.272(a)(4)]

F. The transportation costs of a living organ donor or cadaver. [38 CFR 17.272(a)(59)]

G. Administration of an investigational or experimental (unproven) immunosuppressant drug that is not FDA approved or has not received CHAMPVA approval as an appropriate "off label" drug indication (see Chapter 2, Section 30.8, *Immunosuppression Therapy*).

END OF POLICY